

UNITED STATES DISTRICT COURT  
FOR THE DISTRICT OF NEW JERSEY

FUSION DIAGNOSTIC LABORATORIES,  
LLC.,

Plaintiff,

v.

ATILA BIOSYSTEMS, INC.

Defendant.

Civ. No. 2:24-cv-00184 (WJM)

OPINION

In this breach of contract action, Defendant Atila Biosystems, Inc. (“Defendant”) moves to dismiss the Complaint pursuant to Fed. R. Civ. P. 12(b)(6) for failure to state a claim upon which relief may be granted. ECF No. 11. The Court decides the matter without oral argument. Fed. R. Civ. P. 78(b). For the reasons stated below, Defendant’s motion to dismiss is **GRANTED IN PART AND DENIED IN PART**.

I. BACKGROUND

Plaintiff Fusion Diagnostic Laboratories, Inc. (“Plaintiff”) is a New Jersey independent clinical laboratory that offers diagnostic testing services, including SARS-CoV-2 (“Covid” or “Covid-19”) testing. Compl. ¶ 1. Defendant is a California based manufacturer and supplier of laboratory instruments, reagents, consumables, software, and supplies. *Id.* at ¶ 2. Among the products Defendant markets and sells are Covid testing kits and instruments including the Atila Power Gene 9600 Plus Real Time PCR System (“Analyzer”) and iAMP Covid-19 Detection Kit (“Covid Kit”). *Id.* at ¶ 2.

From about September 28, 2020 to January 9, 2022, Plaintiff paid Defendant a total of \$938,800 for the Analyzer and several lots of Covid Kits. *Id.* at ¶¶ 7, 19. Each Covid Kit contained materials for 100 tests. *Id.* at ¶ 18. On December 21, 2021, Plaintiff received Lot 16 (150 Covid Kits), *id.* at ¶ 21, which purportedly had “irregularities” including false positive test results, inconsistent measurements of controls, and an inordinate amount of invalid results. *Id.* at ¶¶ 27-28. Plaintiff notified Defendant of these irregularities, but Defendant claimed the problem was contamination at Plaintiff’s lab or Plaintiff’s failure to follow testing protocol. *Id.* at ¶ 30. On January 5, 2022, Plaintiff received Lot 31 (200 Covid Kits), *id.* at ¶ 23, which it alleges yielded “high” positive results. *See id.* at ¶¶ 36-68. Due to the defective kits, Plaintiff was not able to “release the test results which severely and irreparably damaged its reputation with Hoboken, Bayonne and Union City”

and was immediately banned from those and other sites. *Id.* at ¶41. After conducting testing on Lot 31, on February 19, 2022, Defendant refunded Plaintiff the Lot 31 purchase price of \$319,800. *Id.* at ¶ 69.

Plaintiff filed suit on January 11, 2024 seeking \$30 million compensatory and punitive damages for loss of business and profits from “extensive” damage to its business reputation. The Complaint pleads breach of contract (Count I), breach of express warranty (Count II), and negligent misrepresentation (Count III). ECF No. 1. Defendant moves to dismiss the Complaint on the grounds that 1) it is immune from liability under the Public Readiness and Emergency Preparedness Act, 42 U.S.C. §§ 247d-6d, 247d-6e (“PREP Act”); 2) Plaintiff fails to identify the contract or warranties that have been breached; 3) New Jersey’s economic loss doctrine bars the claim for negligent misrepresentation; and 4) the Complaint does not support a claim for punitive damage.

## II. DISCUSSION

### A. Motion to Dismiss Standard

Federal Rule of Civil Procedure 12(b)(6) provides for the dismissal of a complaint, in whole or in part, if the plaintiff fails to state a claim upon which relief can be granted. The moving party bears the burden of showing that no claim has been stated. *Hedges v. United States*, 404 F.3d 744, 750 (3d Cir.2005). Dismissal is appropriate only if, accepting all the facts alleged in the complaint as true, the plaintiff has failed to plead “enough facts to state a claim to relief that is plausible on its face.” *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 570 (2007); *see also Umland v. PLANCO Fin. Serv., Inc.*, 542 F.3d 59, 64 (3d Cir. 2008). This assumption of truth is inapplicable, however, to legal conclusions couched as factual allegations or to “[t]hreadbare recitals of the elements of a cause of action, supported by mere conclusory statements.” *Ashcroft v. Iqbal*, 556 U.S. 662 (2009). That is, although a complaint need not contain detailed factual allegations, “a plaintiff’s obligation to provide the ‘grounds’ of his ‘entitlement to relief’ requires more than labels and conclusions, and a formulaic recitation of the elements of a cause of action will not do.” *Twombly*, 550 U.S. at 555. Thus, the factual allegations must be sufficient to raise a plaintiff’s right to relief above a speculative level, *see id.* at 570, such that the court may “draw the reasonable inference that the defendant is liable for the misconduct alleged.” *Iqbal*, 556 U.S. at 678 (citing *Twombly*, 550 U.S. at 556). While “[t]he plausibility standard is not akin to a probability requirement’ ... it asks for more than a sheer possibility that a defendant has acted unlawfully.” *Iqbal*, 556 U.S. at 678.

### B. Immunity Under PREP Act

“The PREP Act protects certain covered individuals—such as pharmacies and drug manufacturers—from lawsuits during a public-health emergency.” *Maglioli v. Alliance HC Holdings LLC*, 16 F.4th 393, 400 (3d Cir. 2021); 42 U.S.C. § 247d-6d(i)(2). If the Secretary

of the Department of Health and Human Services (the “Secretary”) “deems a health threat a public-health emergency, he may publish a declaration in the Federal Register recommending certain ‘covered countermeasures.’” *Maglioli*, 16 F.4<sup>th</sup> at 400 (citing 42 U.S.C. § 247d-6d(b)(1)). “Covered countermeasure” includes a drug, biological product, or device authorized for emergency use. 42 U.S.C. § 247d-6d (i)(1)(C). In March 2020, the Secretary declared Covid-19 a public-health emergency and recommended a series of covered countermeasures. *Maglioli*, 16 F.4<sup>th</sup> at 401 (citing Declaration Under the PREP Act for Medical Countermeasures Against COVID-19 (“Declaration”), 85 Fed. Reg. 15,198, 15,201, 15,202 (Mar. 17, 2020)).

Once the PREP Act is invoked by the Secretary, a “covered person” is immune from “suit and liability under Federal and State law with respect to all claims for loss caused by, arising out of, relating to, or resulting from the *administration to or the use by an individual* of a covered countermeasure,” 42 U.S.C. § 247d-6d(a)(1) (emphasis added), except for claims of “willful misconduct” as defined in the PREP Act, § 247d-6d (d)(1). Immunity under this subsection applies to “any claim for loss that has a causal relationship with the *administration to or use by an individual* of a covered countermeasure.” *Id.* at § 247d-6d(a)(2)(B) (emphasis added). Where the PREP Act applies, the scope of immunity is broad. *Maglioli*, 16 F.4<sup>th</sup> at 401. Plaintiff does not dispute that Defendant is a “covered person” or that its Covid tests are “covered countermeasures,” but is correct that Defendant is not immune under the PREP Act from Plaintiff’s state law breach of contract claims.

Although the PREP Act does not define “administration,” the Secretary defines “Administration of a Covered Countermeasure,” as the “physical provision of the countermeasures to recipients, or activities and decisions directly relating to public and private delivery, distribution, and dispensing of the countermeasures to recipients...” Declaration, at 15198-01. Hence PREP Act immunity is typically asserted in cases where plaintiffs are individual recipients (or suing on behalf of individual recipients) claiming harm from the actual administration, delivery, or distribution of the covered countermeasure. *See e.g., Fust v. Gilead Sciences, Inc.*, No. 23-2853, 2024 WL 732965 (E.D. Ca. Feb. 21, 2024) (concluding PREP Act immunizes manufacturer of antiviral drug, remdesivir, against state claims by patients who were prescribed, purchased, and ingested the drug). This is consistent with the purpose of such immunity, which is to “embolden caregivers, permitting them to administer certain encouraged forms of care (listed COVID “countermeasures”) with the assurance that they will not face liability for having done so.” *Est. of Maglioli v. Andover Subacute Rehab. Ctr. I*, 478 F. Supp.3d 518, 529 (D.N.J. 2020), *aff’d sub nom. Maglioli v. All. HC Holdings LLC*, 16 F.4th 393 (3d Cir. 2021).

Here, Plaintiff does not allege loss from the “administration to or the use by an individual” of a covered countermeasure, but rather sues as a buyer seeking to hold the seller liable for the sale of allegedly defective Covid tests. *Cf. Est. of Maglioli*, 478 F. Supp.3d at 529 (noting plaintiffs’ claims of failure to exercise due care were not preempted by PREP Act where plaintiffs did not allege injuries arose from administration of

countermeasures); *Coleman v. Intensive Speciality Hosp., LLC*, No. 21-0370, 2022 WL 17779323, at \*5 (W.D. La. Dec. 19, 2022) (finding claims of failure to follow proper standard of care were not covered by PREP Act where plaintiff did not allege administration or use of countermeasure somehow caused decedent's death). Nothing in the language of the PREP Act suggests that a manufacturer is immune from suit brought by the buyer in a commercial breach of contract dispute over the quality of goods sold.

### C. Breach of Contract (Count I)

A breach of contract claim requires a party to “prove a valid contract between the parties, the opposing party's failure to perform a defined obligation under the contract, and the breach caused the claimant to sustained [sic] damages.” *EnviroFinance Grp., LLC v. Env't Barrier Co., LLC*, 440 N.J. Super. 325, 345 (App. Div. 2015). Plaintiff states that an implied in fact contract existed between the parties. Pl. Opp'n Br. at 18. “[C]ontracts implied in fact are no different than express contracts, although they exhibit a different way or form of expressing assent than through statements or writings. Courts often find and enforce implied promises by interpretation of a promisor's word and conduct in light of the surrounding circumstances.” *Wanaque Borough Sewerage Auth. v. Twp. of W. Milford*, 144 N.J. 564, 574 (1996); *Hercules Inc. v. United States*, 516 U.S. 417, 424 (1996) (“An agreement implied in fact is founded upon a meeting of minds, which, although not embodied in an express contract, is inferred, as a fact, from conduct of the parties showing, in the light of the surrounding circumstances, their tacit understanding.” (internal quotes and citation omitted)). “[D]espite the difference in the way the contracts are created, an implied-in-fact contract is generally “as binding as [an] express contract.” *Comprehensive Neurosurgical, P.C. v. Valley Hosp.*, 257 N.J. 33, 70 (2024) (citing *Troy v. Rutgers*, 168 N.J. 354, 365 (2001)).

Defendant argues that Plaintiff fails to identify any particular contract or provisions that have been breached. However, “[t]here is some variety in New Jersey caselaw as to whether a plaintiff must identify specific contract provisions to survive a motion to dismiss.” *Motamed v. Chubb Corp.*, No. 15-7262, 2016 WL 1162853, at \*4 (D.N.J. Mar. 24, 2016). *Compare Fabbro v. DRX Urgent Care, LLC*, 616 Fed. App'x 485, 487 (3d Cir. 2015) (affirming dismissal of breach of contract claim because plaintiffs “failed to cite a single provision” of the agreement that was breached) with *Latraverse v. Kia Motors of Am., Inc.*, No. 10-6133, 2011 WL 3273150, at \*2 (D.N.J. July 27, 2011) (“Under the Federal Rules, a plaintiff is not required to include the contract with the complaint, or allege the specific provisions violated in the contract.”). “[A]ll of these opinions agree that the underlying goal of the pleading standard in a breach of contract case is notice.” *Motamed*, 2016 WL 1162853, at \*4. “Where courts have dismissed claims that fail to identify specific contract provisions, generally the claims lack specificity not just as to the contract provisions but as to the entire basis of the suit, thus failing to put the defendant on notice of the plaintiff's claims.” *Id.* (declining to dismiss claims despite failure to specify contract provisions that were breached because defendant was adequately put on notice of Plaintiffs’



claims and grounds upon which they rested). Here, the Complaint sufficiently alleges that the parties agreed to the sale and purchase of Covid Kits and that in breach of that agreement, Lots 16 and 31 were defective. Defendant is adequately on notice of what Plaintiff claims constituted breach of contract. Defendant's motion to dismiss the breach of contract claim is **denied**.

#### D. Breach of Express Warranty (Count II)

Under New Jersey law, in order to state a cause of action for breach of express warranty, Plaintiffs must properly allege: (1) that Defendant made an affirmation, promise or description about the product; (2) that this affirmation, promise or description became part of the basis of the bargain for the product; and (3) that the product ultimately did not conform to the affirmation, promise or description. *New Hope Pipe Liners v. Composites One, LCC*, No. 09-3222, 2009 WL 4282644, at \*5 (D.N.J. Nov. 30, 2009); N.J.S.A. § 12A:2–313. Plaintiff alleges that Defendant warranted “per the Terms and Conditions of Sale” and “various and numerous representations” that each product sold would be free of defect, but that Defendant violated those “various express warranties.” Compl. ¶¶ 78-80, 81. These statements, however, are simply bald assertions that fail to identify any specific affirmations or promises by Defendant. Thus, the breach of express warranty claim as pled cannot survive a motion to dismiss. *See Simmons v. Stryker Corp.*, 2008 WL 4936982, at \*2 (D.N.J. Nov. 17, 2008) (dismissing without prejudice a claim that was “devoid of any ‘factual matter’ to support the existence of an express warranty”); *Arlandson v. Hartz Mountain Corp.*, 792 F. Supp.2d 691, 707 (D.N.J. 2011) (same); *Fishman v. Gen. Elec. Co.*, No. 12-00585, 2013 WL 1845615, at \*5 (D.N.J. Apr. 30, 2013) (dismissing without prejudice for failure to identify in amended complaint any specific affirmations of fact or promises). Plaintiff's express warranty claim is **dismissed without prejudice**.

#### E. Negligent Misrepresentation (Count III)

Plaintiff's negligent misrepresentation claim is barred by New Jersey's economic loss doctrine. The “economic loss doctrine ‘prohibits plaintiffs from recovering in tort economic losses to which their entitlement only flows from a contract.’” *Bracco Diagnostics, Inc. v. Bergen Brunswig Drug Co.*, 226 F. Supp.2d 557, 562 (D.N.J. 2002) (citing *Duquesne Light Co. v. Westinghouse Elec. Co.*, 66 F.3d 604, 618 (3d Cir. 1995)). “[A] seller's duty of care generally stops short of creating a right in a commercial buyer to recover a purely economic loss.” *Spring Motors Distributors, Inc. v. Ford Motor Co.*, 98 N.J. 555, 579–80 (1985). “[E]conomic loss encompasses actions for the recovery of damages for costs of repair, replacement of defective goods, inadequate value, and consequential loss of profits.” *Alloway v. Gen. Marine Indus., L.P.*, 149 N.J. 620, 627 (1997). Where “a product fails to fulfill a purchaser's economic expectations, contract principles, particularly as implemented by the U.C.C., provide a more appropriate analytical framework.” *Id.* at 628. The allegations here are of “massive financial losses as a result of being supplied defective kits,” loss of business, and “extensive damage” to

business reputation. Compl. ¶¶ 70-71. These are indisputably economic harms unaccompanied by any claims of physical injury.

Moreover, while under New Jersey law, a tort remedy may arise from a contractual relationship where the “breaching party owes an independent duty imposed by law,” see *Saltiel v. GSI Consultants, Inc.*, 170 N.J. 297, 316 (2002), Plaintiff has not pled that Defendant owed Plaintiff any duty independent of any duties under contract. Nor has Plaintiff alleged tortious conduct extraneous to the contract. See *Emerson Radio Corp. v. Orion Sales, Inc.*, No. 95-6455, 2000 WL 49361, at \*7 (D.N.J. Jan. 10, 2000) (noting whether “allegedly tortious conduct is extraneous to the contract” is “critical issue”), *aff’d in part, rev’d in part on other grounds*, 253 F.3d 159 (3d Cir. 2001). The negligent misrepresentation claim is **dismissed without prejudice**.

#### F. Punitive Damages

A punitive damages claim is governed by the New Jersey Punitive Damages Act, N.J.S.A. § 2A:15-5.9, which requires that a plaintiff prove “by clear and convincing evidence” that the defendant’s acts or omissions caused the harm and “were actuated by actual malice or accompanied by a wanton and willful disregard of persons who foreseeably might be harmed by those acts or omissions.”<sup>1</sup> N.J.S.A. § 2A:15-5.12. Dismissal of a punitive damages claim is typically premature because malice and willful disregard are “fact-specific inquir[ies] requiring examination of Defendant’s intent and knowledge.” *Daloisio v. Liberty Mut. Fire Ins. Co.*, 754 F. Supp.2d 707, 710 (D.N.J. 2010). In this case, apart from a conclusory assertion of “malicious” conduct and “purposeful disregard,” Plaintiff has failed to plead any facts that show actual malice or wanton and willful disregard.

Dismissal is also appropriate when “the asserted causes of action expressly bar the imposition of punitive damages.” *Naporano Iron & Metal Co. v. Am. Crane Corp.*, 79 F. Supp.2d 494, 512 (D.N.J. 1999). Generally, “[w]ith rare exception, punitive damages are not available in an action for a breach of contract” under New Jersey law. *Buckley v. Trenton Saving Fund Soc.*, 111 N.J. 355, 369–70 (1988). Any exceptions depend on the “nature of the parties’ relationship or a special duty imposed on the breaching party.” *Naporano Iron*, 79 F. Supp.2d at 513 (citing *Sandler v. Lawn-A-Mat Chem. & Equip. Corp.*, 141 N.J. Super. 437, 449 (App. Div. 1976) (listing exceptions permitting imposition of punitive damages for breach of marital contract, breach of statutory duty, or certain breaches by the non-breaching party’s fiduciary); *W.A. Wright, Inc. v. KDI Sylvan Pools, Inc.*, 746 F.2d 215, 217 (3d Cir. 1984) (“These special relationships [for which exceptions had been found] impose a duty of trust upon the contracting entities. It is the breach of this trust, rather than the breach of the contract, which gives rise to an award of punitive


<sup>1</sup> “Actual malice” is defined as “an intentional wrongdoing in the sense of an evil-minded act.” N.J.S.A. § 2A:15-5.10. “Wanton and willful disregard” is defined as “a deliberate act or omission with knowledge of a high degree of probability of harm to another and reckless indifference to the consequences of such act or omission.” *Id.*

damages.”). Plaintiff has not alleged any special duty. The punitive damages claim is **dismissed without prejudice**.

### III. CONCLUSION

For the reasons noted above, Defendant’s motion to dismiss is **granted in part and denied in part**. Counts II, III, and the punitive damages claim are **dismissed without prejudice**. Plaintiff may file an amended complaint, consistent with the rulings in this Opinion, within thirty days.

Date: June 16, 2024

  
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WILLIAM J. MARTINI, U.S.D.J.